

PTO/SB/21 (08-03)

Approved for use through 08/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/619,777
	Filing Date	July 15, 2003
	First Named Inventor	W.H. ROARK
	Art Unit	1614
	Examiner Name	
Total Number of Pages in This Submission	Attorney Docket Number	PC25131A

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Copies of Cited Art Return Postcard
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Claude F. Purchase, Jr.
Signature	<i>Claude F. Purchase Jr.</i>
Date	January 16, 2004

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
Typed or printed name	Virginia J. Cook		
Signature	<i>Virginia J. Cook</i>	Date	January 16, 2004

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PC25131A

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

APPLICANT : WILLIAM HOWARD ROARK EXAMINER : UNKNOWN
SERIAL NO. : 10/619,777 ART UNIT : 1614
FILED : JULY 15, 2003 CONFIRM. NO. : 8783
FOR : COMBINATION OF AN ALLOSTERIC ALKYNE INHIBITOR
OF MATRIX METALLOPROTEINASE-13 WITH CELECOXIB
OR VALDECOXIB

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97-1.98

Commissioner for Patents
PO BOX 1450
Alexandria, VA 22313-1450

Dear Sir:

This paper is an Information Disclosure Statement Under 37 C.F.R. §§ 1.97-1.98
for the above-identified patent application.

Remarks start on page 2.

REMARKS

Claims 1-10 are pending in the application.

The currently pending claims are directed to a combination comprising valdecoxib, or a pharmaceutically acceptable salt thereof, and an allosteric alkyne inhibitor of MMP-13, or a pharmaceutically acceptable salt thereof, a pharmaceutical composition comprising the combination, and a method of treating a disease or disorder using the combination. Applicants' instant paper does not amend the claims.

Information Disclosure Statement

Applicant herein makes available to the Patent and Trademark Office the art cited in the enclosed Information Disclosure Statement ("IDS") on Form(s) PTO/SB/08A and/or PTO/SB/08B. Copies of U.S. patents and patent application publications, if any, cited in the IDS are not provided. Applicant understands that the Patent and Trademark Office has asked that they not be provided in view of their ready availability to the Examiner via electronic means. Copies of all other cited art are provided.

Applicant also makes available to the Patent and Trademark Office the following co-pending applications:

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/620,174

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC INHIBITOR OF MATRIX

METALLOPROTEINASE-13 WITH CELECOXIB OR VALDECOXIB

ART UNIT: UNKNOWN

APPLICANT'S DOCKET NO.: PC25036A

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/619,662

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC CARBOXYLIC INHIBITOR OF
MATRIX METALLOPROTEINASE-13 WITH CELECOXIB OR
VALDECOXIB

ART UNIT: UNKNOWN

APPLICANT'S DOCKET NO.: PC25132A

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/619,663

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC INHIBITOR OF MATRIX
METALLOPROTEINASE-13 WITH A SELECTIVE INHIBITOR OF
CYCLOOXYGENASE-2 THAT IS NOT CELECOXIB OR VALDECOXIB

ART UNIT: UNKNOWN

APPLICANT'S DOCKET NO.: PC25207A

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/620,173

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC ALKYNE INHIBITOR OF MATRIX
METALLOPROTEINASE-13 WITH A SELECTIVE INHIBITOR OF
CYCLOOXYGENASE-2 THAT IS NOT CELECOXIB OR VALDECOXIB

ART UNIT: UNKNOWN

APPLICANT'S DOCKET NO.: PC25208A

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/619,769

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC CARBOXYLIC INHIBITOR OF
MATRIX METALLOPROTEINASE-13 WITH A SELECTIVE INHIBITOR OF
CYCLOOXYGENASE-2 THAT IS NOT CELECOXIB OR VALDECOXIB

ART UNIT: 1614

APPLICANT'S DOCKET NO.: PC25209A

The Examiner is respectfully requested to consider carefully the complete text of the cited references in connection with the examination of the above-identified application in accord with 37 CFR §1.104(a), including consideration of the claims.

It is respectfully requested that all cited references considered by the Examiner be listed in the "References Cited" portion of any patent issuing from the instant application (MPEP § 1302.12).

The Commissioner is hereby authorized to charge any other fees that may be required, or credit any overpayment, to deposit account number 23-0455.

The undersigned would welcome a telephone call from the Office to discuss any matters.

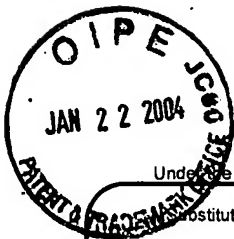
Respectfully submitted,

Date:

January 16, 2004

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Claude F. Purchase, Jr.
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Warner-Lambert Company
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Enc.



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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/619,777
Filing Date	July 15, 2003
First Named Inventor	W. H. Roark
Art Unit	1614
Examiner Name	
Attorney Docket Number	PC25131A

Sheet 1

of 8

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US- 2003/0078276 A1	04-24-2003	ANDRIANJARA, ET AL	
		US- 2003/0130278 A1	07-10-2003	GAUDILLIERE, ET AL	
		US- 2003/0144274 A1	07-31-2003	BUNKER, ET AL	
		US- 6008243	12-28-1999	BENDER, ET AL	
		US- 5948780	09-07-1999	PETERSON, ET AL	
		US- 2002/0156061 A1	10-24-2002	BARVIAN ET AL	
		US- 2002/0151558 A1	10-17-2002	ANDRIANJARA, ET AL	
		US- 2002/0156069 A1	10-24-2002	PICARD ET AL	
		US- 2002/0151555 A1	10-17-2002	BARVIAN ET AL	
		US- 2002/0161000A1	10-31-2002	BARVIAN ET AL	
		US- 6225311 B1	05-01-2001	LEVIN ET AL	
		US- 5929097	07-27-1999	LEVIN ET AL	
		US- 4818819	04-04-1989	E.C. TAYLOR ET AL	
		US- 4902796	02-20-1990	E.C. TAYLOR ET AL	
		US- 5646141	07-08-1997	M.D. VARNEY ET AL	
		US- 4412856	11-01-1983	BRUNNER ET AL	
		US- 5990116	11-23-1999	NUSSBAUMER	
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
		WO 03/032999 A1	04-24-2003	BUNKER ET AL		
		WO 03/033478 A1	04-24-2003	GAUDILLIERE ET AL		
		WO99/52910 A1	10-21-1999	ROBINSON, Ralph		
		WO 00/37107 A2	06-29-2000	MCKEARN ET AL		
		WO 02/064080 A2/A3	08-22-2002	ANDRIANJARA ET AL		
		WO 00/09485 A1	02-24-2000	MCCLURE ET AL		

Examiner
SignatureDate
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Sheet 2

of 8

Complete if Known

Application Number	10/619,777
Filing Date	July 15, 2003
First Named Inventor	W.H. Roark
Art Unit	1614
Examiner Name	
Attorney Docket Number	PC25131A

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		Country Code ³ *Number ⁴ *Kind Code ⁵ (if known)				
		WO0155133 A1	08-02-2001	WATANABE ET AL		
		WO0206513 A2	01-24-2002	HOMA ET AL		
		WO9616046 A2/A3	05-30-1996	GUERRY ET AL		
		WO0040561 A1	07-13-2000	TURNER ET AL		
		WO9816514 A1	04-23-1998	LEVIN ET AL		

Date Considered

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Sheet	3	of	8
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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)	MM-DD-YYYY			
		WO0035906 A2	06-22-2000	LUK ET AL		
		WO0163244 A1	08-30-2001	CHEN ET AL		
		WO02064599 A1	08-22-2002	DYER ET AL		
		WO02064547 A2/A3	08-22-2002	BARVIAN ET AL		
		WO02064598 A1	08-22-2002	HARTER ET AL		

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Signature

Date
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Sheet 5

of 8

Application Number	10/619/777
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First Named Inventor	W.H. ROARK
Art Unit	1614
Examiner Name	
Attorney Docket Number	PG25131A

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		Country Code ² Number ⁴ Kind Code ⁵ (if known)				
		WO0234726 A3/A2	05-02-2002	NOE ET AL		
		WO0234753 A2	05-02-2002	BRONK ET AL		
		EP0935963 A2/A3	08-18-1999	MCCLURE ET AL		
		EP 1138680 A1	10-04-2001	NOE		
		WO01/053274 A1	07-26-2001	BENDER ET AL		
		WO9633181 A1	10-24-1996	NAKAYAMA ET AL		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	6
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of 8

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U. S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

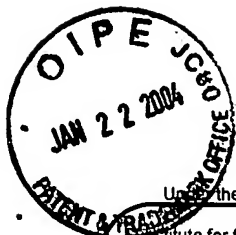
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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	MM-DD-YYYY			
		WO9703967 A1	02-06-1997	ALDOUS ET AL		
		WO9902497 A2/A3	01-21-1999	ALLGEIER ET AL		
		WO 9616046 A2/A3	05-30-1996	GUERRY ET AL		
		JP10195063	07-28-1998			
		WO0044716	08-03-2000	LEVIN ET AL		

Examiner Signature		Date Considered	
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Examiner Name	
Attorney Docket Number	PC25131A
Sheet 7 of 8	

NON PATENT LITERATURE DOCUMENTS

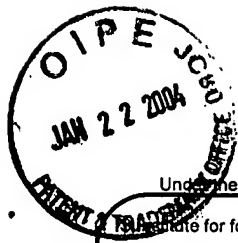
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		MICHAEL G. NATCHUS, et al., "Development of New Carboxylic Acid-Based MMP Inhibitors Derived from Functionalized Propargylglycines", J.Med.Chem. 2001, 44:1060-1071.	
		International Search Report for International Application No. PCT/IB03/03154	
		A.B. DYATKIN, et al., "The Solid Phase Synthesis of Complex Propargylamines Using the Combination of Sonogashire and Mannich Reactions", Tetrahedron Letters, Elsevier Science Publishers, Amsterdam, NL 1998, 39(22)3647-3650	
		E.C. TAYLOR, et al., "Pteridines, 51. A New and Unequivocal Route to C-6 Carbon-Substituted Pterins and Pteridines", J.Org.Chem 1987, 52:3997-4000	
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		JOHN MONTANA & ANDREW BAXTER, "The design of selective non-substrate-based matrix metalloproteinase inhibitors", Current Opinion in Drug Discovery & Development 2000,3(4):353-361	
		CHEN, et al., "Structure-Based Design of a Novel, Potent, and Selective Inhibitor for MP-13 Utilizing NMR Spectroscopy and Computer-Aided Molecular Design", J.Am.Chem. Soc. 2000, 122:9648-9654	
		Aldrich Chemical Company, Milwaukee, WI, 1992, pg. 989, entry 11,770-6	
		VAN DEN BERG WB, Lessons from animal models of osteoarthritis, Curr Opin Rheumatol 2001 Sep; 13(5):452-6, (abstract) Medline [online]. Bethesda, MD, USA: United States National Library of Medicine	
		PENDAS AM, An overview of collagenase-3 expression in malignant tumors and analysis of its potential value as a target in antitumor therapies, Clin Chim Acta 2000 Feb 15;291(2):137-55, (abstract) Medline [online]. NLM	

Examiner Signature	Date Considered
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number 10/619,777

Filing Date July 15, 2003

First Named Inventor W.H. Roark

Art Unit 1614

Examiner Name

Sheet 8

of 8

Attorney Docket Number PC25131A

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		CLARK, et al., "Matrix metalloproteinase inhibitors in the treatment of arthritis", Current Opinion in Anti-inflammatory & Immunomodulatory Investigational Drugs 2000, 2(1):16-25	
		DRAETTA, G. and PAGANO, M. in "Annual Reports in Medicinal Chemistry, Vol. 31.; 1996, Academic Press, San Diego, pp 241-246.	
		POLMAN, C.H., et al., BMJ 2000, 321, 490-4.	
		COHEN, J.A., et al., J. Neuroimmun., 1999, 98, 29-36.	
		FREIJE, JOSE M., et al., "Molecular Cloning and Expression of Collagenase-3, a Novel Human Matrix Metalloproteinase Produced by Breast Carcinomas", J. Biological Chem., 1994; 269(24):16766-16773	
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		Derwent Publications Lt. Abstract No. 2001-514548	
		GOLDMAN, M., et al., "Valdecoxib A Cox-2 Inhibitor for Treatment of Osteoarthritis, Rheumatoid Arthritis, and Primary Dysmenorrhea" Formulary, Advanstar Communications, Cleveland, OH, US, Vol. 37, No. 2, Feb. 2002 (2002-02), pp. 68, 71-74, 76-77	

Examiner Signature	Date Considered
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